The Hungarian Way

To increase their cost-efficiency and become more globally competitive, manufacturers and CROs in the CEE region often turn to local companies for procurement and logistics solutions. One such country is Hungary, which has witnessed a surge in local sourcing activities due to a number of reasons

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Procurement experts of manufacturers and CROs have their tasks cut out to ensure that their multi-country trials are adequately provided with a wide range of properly packaged and distributed supplies, including comparators, rescue medicine or products for basic and complementary therapy. Not only is there a wide portfolio of required products and services, but they should also be procured:

- Based on strict timelines
- With the maximum level of cost-efficiency
- From suppliers who meet the highest standards of industry-specific quality control requirements
- With the widest array of supporting documentation (Certificate of Analysis [COA], Certificate of Conformance [COC] and so forth)

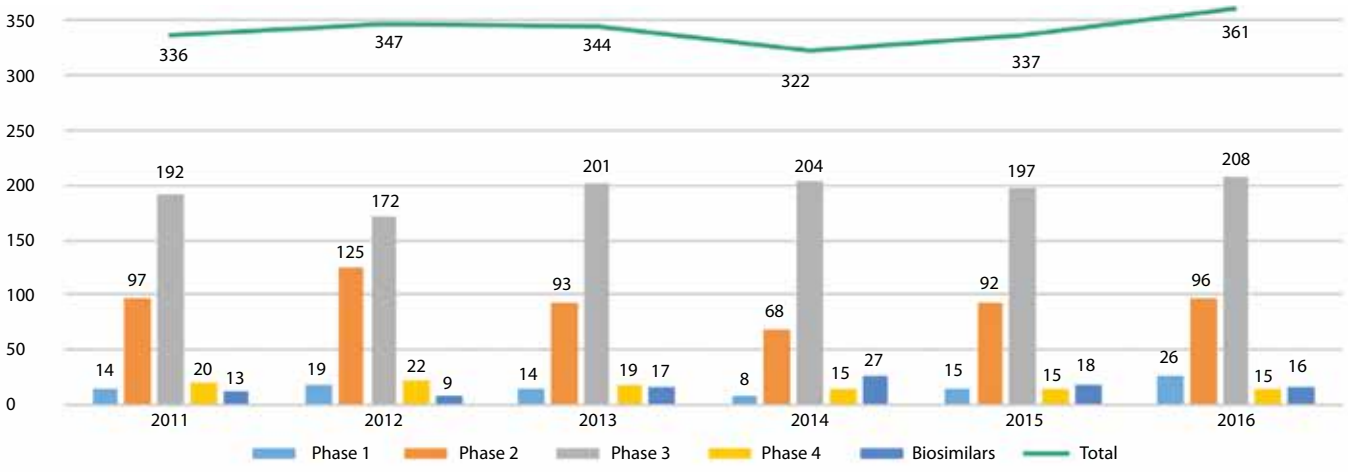
To solve this often contradictory puzzle and successfully meet all the above criteria, supply chain specialists have started to increasingly give preference to local – as opposed to central – sourcing strategies. In these cases, the procurement of clinical trial supplies and related services (like storage, packaging, labelling or distribution for example) are not controlled from a central depot, but organised locally by qualified vendors in each country where the investigator sites are located. This approach could offer multiple advantages, including savings as a result of lower purchasing prices for product supplies; access to products in national languages; decreased logistic costs; and increased speed of supply.

Rise of Hungary

In recent years, countries in Central and Eastern Europe (CEE) have begun to play a more important role within the domain of global clinical trials. Several countries in the region have seen a growing number of their healthcare institutions become qualified investigator sites. Hungary in particular has

	2011	2012	2013	2014	2015	2016
Phase 1	14	19	14	8	15	26
Phase 2	97	125	93	68	92	96
Phase 3	192	172	201	204	197	208
Phase 4	20	22	19	15	15	15
Biosimilars	13	9	17	27	18	16
Total	336	347	344	322	337	361

▲ **Table 1:** Number of clinical trials approved in Hungary (2011-2016)



Source: Division of Clinical Trials, National Institute of Pharmacy and Nutrition, Hungary

▲ **Figure 1:** Number of clinical trials approved in Hungary (2011-2016)

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benefited tremendously from this process; not only have the number of clinical trials grown gradually, but procurement experts have also started to consider the country as a destination for local sourcing strategies ever more frequently. Many sponsors and CROs are now sourcing the full range of clinical trial supplies required for investigator sites in Hungary via local partners, who are also in charge of the storage, labelling and domestic delivery of these products. There are several reasons for this, which are detailed as follows.

Robust Industry

Hungary's rise on the horizon of clinical trial supply services can generally be attributed to a diverse array of factors but, without any doubt, the country's integrated pharmaceutical sector substantially contributed to the process. Traditionally, Hungary has been a regional base for pharma manufacturing, with several multinational companies such as Richter, Egis, Teva and Sanofi maintaining production sites in the country. This has led to the development of a strong support service sector, including organisations specialised in contract manufacturing, temperature-controlled transportation, packaging and labelling, and analytical and laboratory services, among others.

The wholesale distribution system in Hungary is based on a robust network of business relations between manufacturers and a moderately low number of wholesalers. While the registry of the regulatory agency lists more than 140 companies holding licences for wholesaling activities, the majority of these belong to manufacturers and marketing authorisation holders who are not involved in the domestic distribution of products other than their own. The traditional wholesaling activities – including consignment stock holding for manufacturers, warehousing, picking and packing and performing daily deliveries to pharmacies and hospitals – are conducted only by a handful of long established market participants.

This relatively close-knit and hence reliable industrial environment has played a distinctive role in Hungary becoming a common go-to-market for supply chain

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managers of sponsors, CROs and comparator sourcing specialists.

Sectoral Experience

In the past decade, Hungary has enjoyed a gradual increase in the number of clinical trials involving hospitals and other medical institutions serving as domestic investigator sites. Statistics provided by the Division of Clinical Trials at the National Institute of Pharmacy and Nutrition confirm that documentation pertaining to around 320-350 trials on average has been approved between 2011 and 2015. In 2016, the regulatory agency had positively evaluated 361 submitted dossiers for clinical studies – the highest number in the past six years (1).

According to a survey of the Association of Innovative Pharmaceutical Manufacturers, recent statistics put Hungary in the lead group for the number of clinical trials organised in the member states of the EU. Based on this study, Hungary ranks in 10th position in terms of the aggregate number of studies in the EU, and 4th when the ratio between the country's population and the aggregate number of trials organised is taken into consideration.

The same survey highlights the financial importance of clinical studies for the national economy. It indicates that around €110-120 million is being generated annually in tax income as a result of trial-related services performed in Hungary. The study also stipulates that around 20,000 patients directly benefit from access to the newest technologies of therapeutic treatments through their participation in clinical studies (2).

Another sectoral analysis shows that Hungary has been among the top 10 destinations for trials sponsored by various international manufacturers in recent years. In 2015, for example, 65 studies concerning autoimmune diseases were run simultaneously in Hungary– ranking the country as the 6th most commonly selected destination for trials in this specific therapeutic area in the world (3).

Regulatory Oversight

Apart from the solid industrial background and extensive sectoral experience, Hungary also has been an attractive destination for trials as a result of its strong regulatory oversight. The Division of Clinical Trials at the National Institute of Pharmacy and Nutrition is dedicated not only to the validation of the submitted dossiers, but also to the support of all key stakeholders such as sponsors, CROs and site management organisations. The division's regular training programmes assist all stakeholders involved in the pertaining processes (quality control specialists, clinical research associates, vendors and so forth) in order to ensure that they strictly comply with their required regulatory standards, be they Good Distribution Practice, Good Manufacturing Practice or Good Clinical Practice oriented.

The dialogue regarding best practices, experiences and recommendations is extended to all market participants as the sector organises itself exceptionally well in Hungary and holds regular events that bring together key opinion leaders from all relevant areas. In addition, experts involved in the conduct of clinical trials in Hungary can also seek each other's assistance under the aegis of the Hungarian Clinical Trial Management Society – a non-governmental organisation that has been in existence since 2001 and boasts a membership of around 250 professionals.

Secure Supply Chain

Hungarian wholesalers engaged in the provision of supplies for multi-country trials typically work with manufacturers and marketing authorisation holders on the basis of direct supplying contracts. These contracts allow wholesalers to request products for clinical trials purposes straight from manufacturers. As a result, it is possible to acquire larger quantities than what the Hungarian market would generally allow – often with better terms and conditions. A close cooperation of local vendors with manufacturers also translates into better capabilities to quickly service re-supplies and to manage specific expiry date or batch requirements.

Goods procured for clinical study purposes in Hungary pass through the shortest possible wholesale supply chain without a myriad of intermediaries. This system offers substantial benefits by ensuring that the risk of potentially counterfeit products entering the legitimate supply chain is completely eliminated. Historically, Hungary has been considered as one of the safest destinations in the region as the number of investigated cases involving falsified products converges to zero. The very few instances that have been reported typically concerned lifestyle products for weight loss or performance enhancement, and have not included products that can generally be considered for multi-country trials.

The close cooperation between manufacturers and wholesalers also yields the result that preliminary product documentation (like COA or COC, for example) is always exchanged between the different market participants and is hence available most of the time for clinical study supply purposes. In addition, wholesalers who work directly with manufacturers are in the position of meeting additional documentary requirements – like the bovine spongiform encephalopathy/transmissible spongiform encephalopathy statement or the pedigree certificate – and to acquire otherwise difficult-to-obtain documents, such as a medical safety data sheet or an equivalency statement.

Competitive Prices

Cost-efficiency regarding the procurement of clinical trial supplies has been the main driver behind the proliferation of local sourcing activities in Hungary. Enjoying a substantial price advantage over Germany, Ireland and the UK, where central depots are typically located, Hungary has managed to carve out a niche for itself within the realm of clinical trial supply services. Such price differences are particularly relevant where trial requirements include high-value comparators that can be as much as 30-40% cheaper in Hungary than in other EU member states.

Price differentials favour Hungary not only in product procurement, but in other areas of trial-related services as well. Transportation is the classic example; delivering supplies to investigatory sites from a local vendor's warehousing facility is considerably more cost-effective than from a central depot located in another country. This is particularly so if the required products need temperature-controlled transportation or if they include narcotic substances that can only be transported in separate and dedicated vehicles.

Costs of altering secondary packaging can also be lowered as local products in local languages might not necessarily need to be labelled in certain categories of ancillary supplies, such as rescue medicine or products for complementary therapy.

Local sourcing further contributes to the optimisation of waste management. When comparators are sourced through a domestic wholesaler who regularly provides goods for pharmacies and hospitals, unused but still not labelled or repacked trial supplies do not necessarily need to be destroyed. When forecasts for trial supplies have been exaggerated or a study ends prematurely, products already acquired but no longer needed can be diverted back to the domestic distribution cycle.

Favourable Destination

Experts coordinating the purchasing activities for international clinical trials are under constant pressure to further decrease costs associated with the procurement of products and services. At the same time, they are pressed to select vendors that:

- Maintain direct relations with manufacturers
- Can deliver larger quantities of requested products with appropriate documentation
- Are quick with re-supplies that correspond to specific batch and expiry requirements
- Hold international credentials in terms of their quality control systems
- Can serve as one-stop-shops by offering the widest array of trial-related services, such as product sourcing, storage, distribution, packaging or labelling

Local sourcing is by no means a one-size-fits-all solution for the conundrum presented above. As a matter of fact, choosing the option of working with local vendors represents a certain level of additional risk and can introduce an extra layer of complexity in the procurement system. Not every national market is suitable for local sourcing: in some markets, products are only available through secondary or tertiary suppliers; product documentation cannot always be acquired; or the risk of falsified products is considerable. When it comes to local sourcing, the verdict is that it can serve as a useful weapon in the arsenal of procurement managers – but only among the appropriate market conditions and only with suitable and carefully vetted vendors.

For years, Hungary has been an up-and-coming destination favoured by the purchasing managers of sponsors and CROs as it meets all the necessary requirements regarding the security and cost-efficiency of clinical trial supplies. With a strong industrial and regulatory base as well as widespread sectoral experience, the country is expected to continue to grow in the coming years, both in terms of the number of trials and the share of supplies being sourced locally. As a reliable and economically competitive destination for clinical trial supplies, it is foreseen that Hungary will continue championing local procurement in the CEE region. Due to the careful selection of a trusted domestic partner, the Hungarian market allows for all benefits of a local sourcing strategy to be easily and fully harvested.

References

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